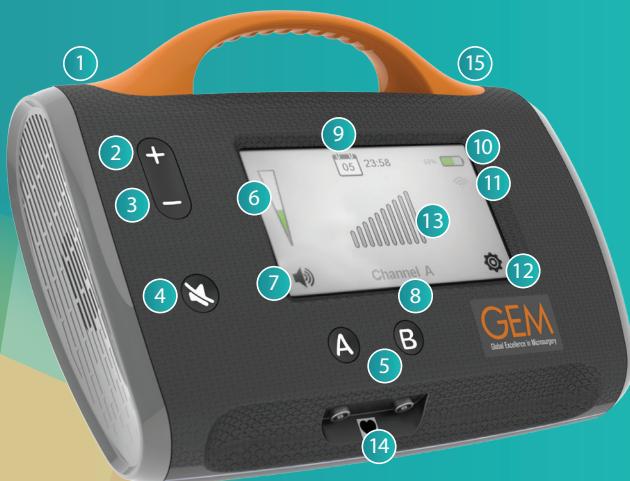


GEM FLOW COUPLER MONITOR MANUAL

PRODUCT SPECIFICATIONS

1. Power Button
2. Volume Toggle Button (increase)
3. Volume Toggle Button (decrease)
4. Mute Button
5. Channel Selection Buttons
6. Volume Slider
7. Mute Button
8. Channel Selection
9. Date/Time
10. Battery Indicator
11. Wi-Fi Indicator
12. Settings Icon
13. Visual Indicator Audible Sound
14. Doppler Lead Receptacles
15. Power Cord Port



Powering Up the Doppler Monitor

1. Turn on the GEM FLOW COUPLER Monitor by pressing the power button on the back of the device.

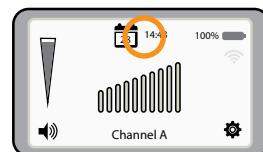
2. After the device has powered on, the following screen appears.

From this screen you can mute device, adjust the volume, change the channel selection, set the date and time, and access the Settings Screen by clicking on the respective icons.

Note: On initial power-up, you may be prompted to create a password. This is not required and may be skipped for immediate local monitoring. The subsequent sections describe the setup for remote connectivity, if desired.

3. Set the date and time

To set the date and time, press the Calendar/time icon on the screen, and use the QWERTY keyboard to set the current date and time.



Setting Up Wi-Fi

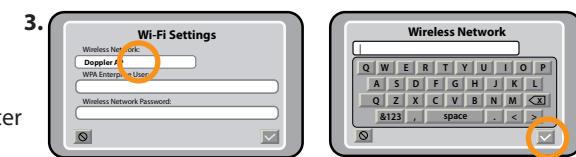
Note: This section includes instructions for configuring connection to a WPA2-PSK network. For detailed instructions on configuring other types of networks, refer to the GEM FLOW COUPLER Monitor IT Setup Guide (MS-14193).



1. To access or change the Wi-Fi settings, press the Settings icon, followed by the Wi-Fi button.

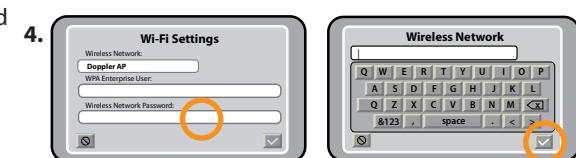


2. Press and hold the first empty field until the Wi-Fi Selection screen appears.



3. Press and hold the Wireless Network field, then type the name of your wireless network using the QWERTY keyboard. This is case sensitive, so be sure to type the name exactly as it appears on your wireless network. After you type it in, press the green button to save it.

Note: The Enterprise User field is unused when connecting via WPA2-PSK



4. Press and hold the Wireless Network Password field; then type the wireless network password using the QWERTY keyboard.

Wait until the Wi-Fi is connected. If the connection is successful, the Wi-Fi indicator will remain solid black.

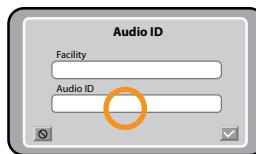
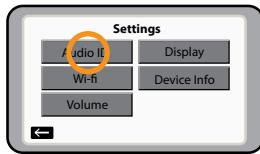
Set Up Audio ID and Facility

Audio ID Settings Screen brings up two fields in which to input Facility information and Audio ID. Once either is pressed a QWERTY keyboard is displayed.

NOTE: Please do not input private patient or hospital information into these fields. Use nicknames instead.

Press the arrow bar to go back to the main settings screen. ←

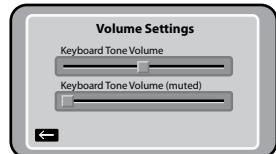
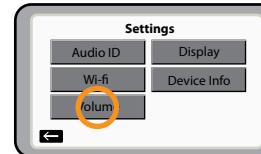
Every device registered to your hospital will have to use the same Facility ID in order to read to your GEMflow Station.



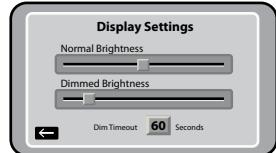
For security, when initially attempting to set up Audio ID and Facility ID settings, the device will prompt to set a password to ensure these cannot be modified by unauthorized personnel.



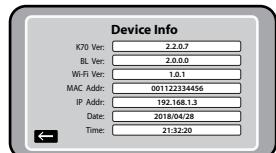
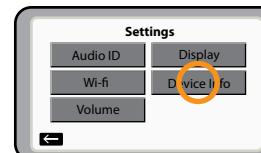
Volume Settings Screen contains two sliders where you can change the Keyboard Tone Volume when the volume is active (top bar) and when the volume is muted (bottom bar).



Display Settings Screen contains two sliders where you can change the Normal Brightness OR Dimmed Brightness and the duration of each.



Device Info Screen contains technical specifications including versions of the hardware and software, MAC and IP addresses, and the date and time.

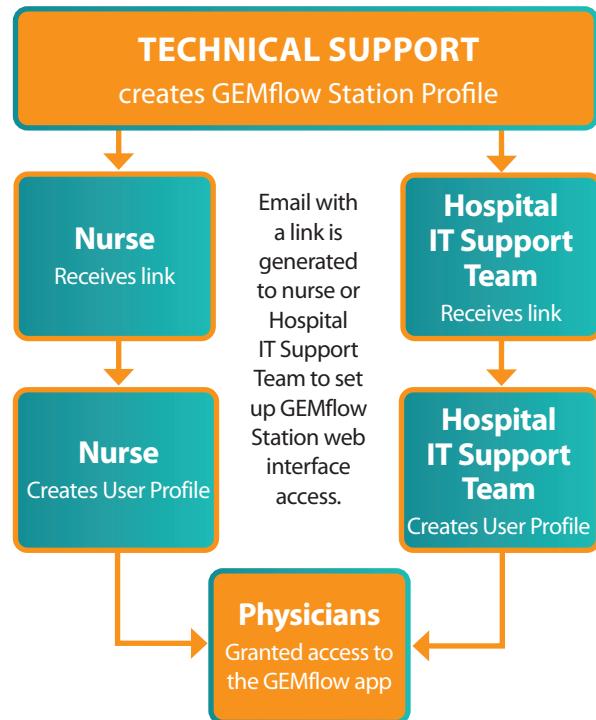


In order for the blood flow audio to feed to the Station and the App, your device (monitor) must be connected to Wi-Fi. Please check the Wi-Fi has been established and connected before each use.

Roles and Assignment of FLOW COUPLER System

The GEM FLOW COUPLER Monitor has the ability to record 15 seconds of audio from Channel A and/or Channel B. Once the monitor Wifi has been established and the Channels are connected, the audio files are transmitted to the GEMflow station and the latest downloaded audio file will be available on the GEMflow smartphone application (Android and/or IOS).

The roles and responsibilities for setup and management of the accounts are graphically presented and described in the section below.



GEMflow Station

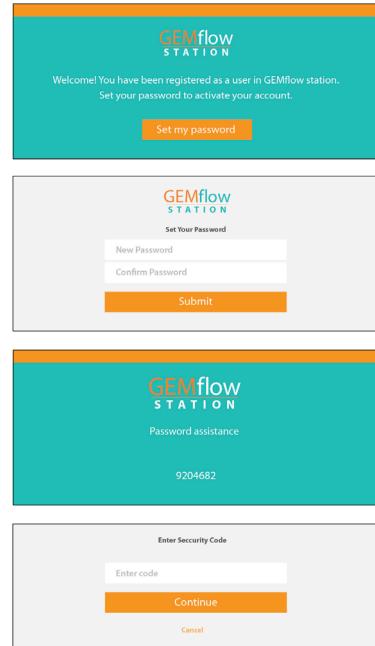
Devices: The term "device" refers to the GEM FLOW COUPLER Monitor.

Users: The term "users" refers to the Microsurgeons.

The GEMflow Station is used to create and manage user profiles and assign users to their device(s). You can also listen to blood flow audio on the Station for devices that are assigned and in use.

Open a web browser and enter the following URL: <https://GEMflowstation.com/login>

Note: Web-based interface may be revised over time.



Activate Account

Once a user is registered they will receive an email. Click on the 'set my password' button to be directed to the GEMflow Station or type in the url if you are experiencing issues with redirection.

Once you click on the 'set my password button' your browser will open in a new window to set your password.

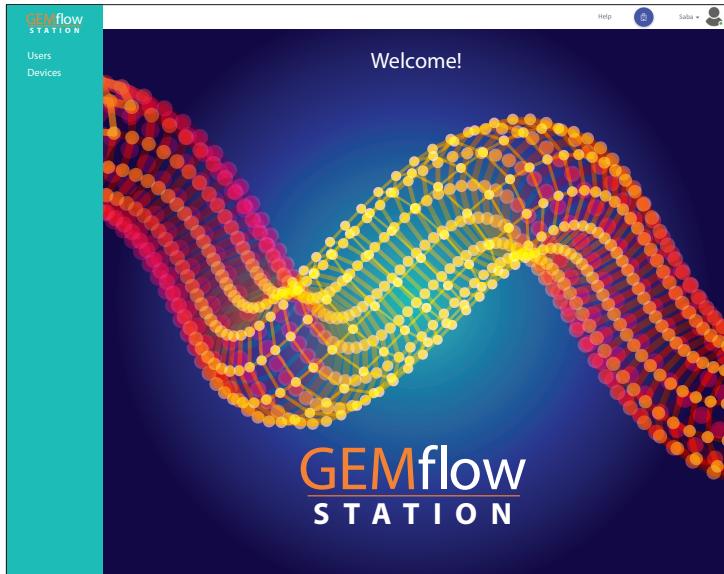
Once you set your password, initial login requires security code verification. An email with a security code will be sent to the new user.

Enter the code you received into the web interface screen prompted after you set up your new password.

This is a two step login feature. You will need to enter a security code every time you access the system.

After 2 minutes of inactivity the system will alert you that your session is about to expire. If you do not select the "Keep me signed in" button, the system will automatically log you out.

After logging into the GEMflow Station, you will see your dashboard as reflected below. There are two main controls on the left column, **Users** and **Devices**. Click on the tab to navigate to the desired page.



Users: When registering a new user (Microsurgeon), click the REGISTER button at the top left of your screen.

A screenshot of the 'Users' management interface. The left sidebar shows 'Users' and 'Devices'. The main content area is titled 'Users' and contains a table with two rows of data. A 'Register' button is highlighted with a red circle. At the bottom, there are navigation links: 'first', 'prev', 'next', and 'last'. The table data is as follows:

Name	Email	Phone Number	Role	Status
John Smith	john.smith@hospital.com	4567891	User	Active
Tracy Smith	tracy.smith@hospital.com	3032217	User	Inactive

The Register User screen will appear, allowing you to input new user's information into the system. When finished, click the Register button to save the profile.

A modal window titled 'Register User'. It contains three input fields: 'Name' (text input), 'Email' (text input), and 'Phone Number' (text input). At the bottom are 'Register' and 'Cancel' buttons, with 'Register' highlighted with a red circle. The footer shows the URL 'myar.nahamed@gmail.com' and the ID '9023032217'.

Edit User Profile: To edit a profile, click the EDIT button on the far right of the user profile you would like to change.

The screenshot shows the 'Users' section of the GEMflow STATION interface. On the left, there's a sidebar with 'Users' and 'Devices' options. The main area displays a table titled 'User List' with two entries: John Smith and Tracy Smith. The 'Status' column for John Smith contains an edit icon (pencil), which is circled in red. Navigation buttons at the bottom include 'first', 'prev', 'next', and 'last'.

The following screen will appear. Once you have updated the user profile, click the 'Update' button to save the new information. (By clicking CANCEL no edits will be stored.)

This is a modal dialog titled 'Edit User'. It contains three input fields: 'Name' (John Smith), 'Email' (john.smith@hospital.com), and 'Phone Number' ((XXX) XXX XXXX). At the bottom are two buttons: a blue 'Update' button with a white outline and a teal 'Cancel' button with a white outline. The 'Update' button is circled in red.

Delete User Profile: If you need to delete a User profile, select the user's name.

The screenshot shows the 'Users' section of the GEMflow STATION interface. The 'User List' table has one entry: Midhun. In the top right corner of the interface, there's a user profile icon with a delete icon (trash can) next to it, which is circled in red. Navigation buttons at the bottom include 'first', 'prev', 'next', and 'last'. A message at the bottom says 'Showing 1-2 of 2 users'.

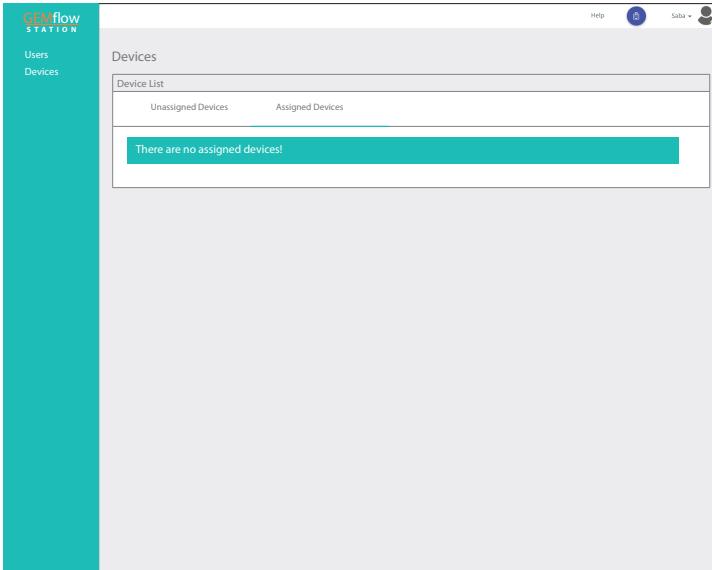
The following screen will appear. Click the DELETE button on the far right.

This is a detailed view of a user profile for 'Midhun'. It shows basic information: Role (User), Email (john.smith@hospital.com), and Phone (1234567891). In the top right corner, there's a 'Delete' button with a trash can icon, which is circled in red. Navigation buttons at the top include 'Back' and 'Help'.

Devices: The Device screen allows you to see newly registered Devices and Audio IDs, assign them to users (Microsurgeons) and remove devices from your list.

The default view for the Device tab is your assigned devices. You can toggle between unassigned devices and assigned devices by clicking on their title.

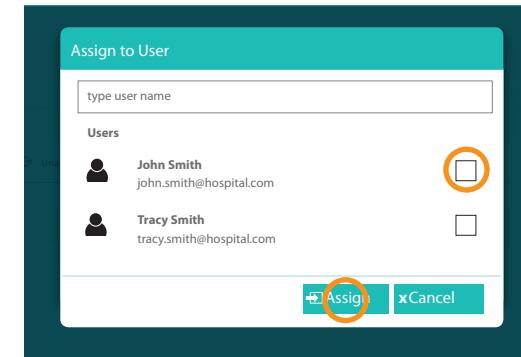
The first time you access the Devices screen, the assigned list screen will look like this:



When a new Audio ID is registered to the Hospital's identifying Facility ID, it will automatically populate within the GEMflow Station "Unassigned Devices" tab. When the Nurse or Hospital IT is ready to Assign the device/audio id to a user (Microsurgeon), they will click the assign button on the far right of the device list as seen in the image below.

Facility Id	Audio Id	Phone No	Registration date	Actions	
				Assign	Remove
Fid 1	pid16		28-04-2017	<input type="button" value="Assign"/>	<input checked="" type="button" value="Remove"/>
Fid 1	pid15		28-04-2017	<input type="button" value="Assign"/>	<input checked="" type="button" value="Remove"/>
Fid 1	pid14		28-04-2017	<input type="button" value="Assign"/>	<input checked="" type="button" value="Remove"/>
Fid 1	pid13		28-04-2017	<input type="button" value="Assign"/>	<input checked="" type="button" value="Remove"/>
Fid 1	pid12		28-04-2017	<input type="button" value="Assign"/>	<input checked="" type="button" value="Remove"/>
Fid 1	pid11		28-04-2017	<input type="button" value="Assign"/>	<input checked="" type="button" value="Remove"/>
Fid 1	pid10		28-04-2017	<input type="button" value="Assign"/>	<input checked="" type="button" value="Remove"/>
Fid 1	pid1		28-04-2017	<input type="button" value="Assign"/>	<input checked="" type="button" value="Remove"/>

A user list will populate like the image below. From the list, the nurse/ hospital IT will select the user by clicking into the box next to their information and hitting the assign button.



Hospital Admin can see all registered hospitals assigned to their Facility ID by clicking on the hospital view option. You have the ability to toggle between hospital dashboards simply by clicking on the facility location of choice from the list that populates. If your Hospital only has one facility, you will not see other facility locations.

Name	Email	Phone Number	Role	
John Smith	john.smith@hospital.com	1234567891	User	Active
Tracy Smith	tracy.smith@hospital.com	9876543211	User	Inactive

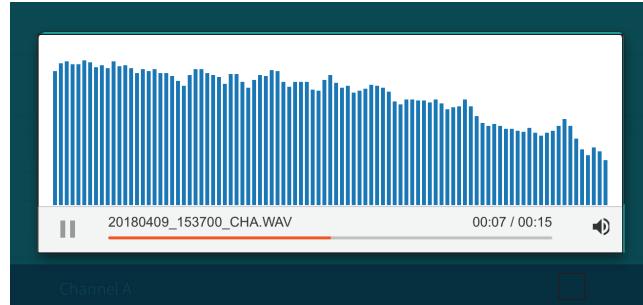
In order to listen to bloodflow recordings on the web interface, select the Audio ID from your device list by clicking on it.

Facility Id	Audio Id	Phone No	Registration date
Fid 1	AI001		28-04-2017
Fid 1	AI002		28-04-2017
Fid 1	AI003		28-04-2017
Fid 1	AI004		28-04-2017
Fid 1	AI005		28-04-2017
Fid 1	AI006		28-04-2017
Fid 1	AI007		28-04-2017
Fid 1	AI008		28-04-2017

Once you select the Audio ID, a similar screen to the one below will appear.
(This is an example if both Channel A and B have files available for download).

Choose the one you would like to listen to and a pop up will appear that allows you to play the audio recording as well as follow the visual sound waves.

The screenshot shows the 'Device files' section of the GEMflow STATION web interface. On the left, there's a sidebar with 'Users' and 'Devices' options. The main area is titled 'Device files' and shows two sections: 'Channel A' and 'Channel B'. Under 'Channel A', there are three rows of audio files with download icons and timestamps: '20180409_153700_CHA.WAV' (09-04-18 04:42:13), '20180409_153048_CHA.WAV' (09-04-18 04:36:02), and '20180409_104427_CHA.WAV' (09-04-18 11:49:42). Under 'Channel B', there are two rows: '20180409_153805_CHB.WAV' (09-04-18 04:43:18) and '20180409_153154_CHB.WAV' (09-04-18 04:37:08). At the bottom, there are navigation buttons for 'first', 'prev', 'next', and 'last'.



To log out of the web interface, select your profile icon in the top right. A drop-down menu will appear; click the Log Out option.

The screenshot shows the 'Users' list page of the GEMflow STATION web interface. The left sidebar has 'Users' and 'Devices' options, and the top right shows a user profile for 'Saba' with a 'Logout' link. The main area is titled 'Users' and contains a table of users:

Name	Email	Phone Number	Role	Status
John Smith	john.smith@hospital.com	4567891	User	Active
Tracy Smith	tracy.smith@hospital.com	3032217	User	Inactive

At the bottom, it says 'Showing 1-2 of 2 users' and has navigation buttons for 'first', 'prev', 'next', and 'last'.



Audio Access:

The GEM FLOW COUPLER Monitor can upload 15 seconds of the audio recorded from both probe channels to an audio database. This audio can be accessed from the GEMflow station or the GEMflow mobile application. However, the Wi-Fi has to be established and the channels must be connected.

Download the App:

Use your mobile device, launch the App Store (if on IOS) or Play Store (if on Android).

Click the Search button and enter "GEMflow". Download the app.

Note: App interface may be revised over time.

Launch the App:

Click on the GEMflow icon to launch the app.

Login:

The login (email address) and password will be assigned by the hospital and nurse managing GEM FLOW COUPLER Monitor that you wish to download audio from.

Enter the email and password and click "login".

App Functions:

Four buttons across the bottom of the app provide access to the functions in the app:

Home: GEM logo and home screen.

Audio: Allows access to download audio from the assigned GEM FLOW COUPLER Monitor and Audio IDs.

To download audio from a GEM FLOW COUPLER Monitor, first specify the Facility and then select the device from the list of available devices. Next, click the orange download button. The download may require a few minutes to complete.

History: A history of the last three recordings requested.

If available, the audio from Channels A and B will be loaded and can be played or paused from control button.

Settings: Logout function, contact support, application version

The Settings Page contains a logout button for security purposes only.

The screenshots illustrate the GEMflow mobile application's user interface. The first screen shows the login page with fields for Username and Password, and links for Forget Password? and Help. The second screen is the Home screen, which features a large GEMflow logo and navigation icons for Home, Settings, History, and Logout. The third screen, 'Settings', displays user information (John Smith, johnsmith@hospital.com), facility details (Example Facility, ExampleDevice1-4), and links for Website, Phone, Application Version, and Logout. The fourth screen, 'History', shows a list of three recorded audio sessions with details like Date, Time, Channel, and Duration, along with play/pause controls and a progress bar.

Security and IT Recommendations

Due to the scale, management, and security requirements of individual hospital and users of the GEM FLOW COUPLER Monitor, security and IT procedures and protocols must be enforced by the hospitals.

Baxter recommends the following good practices to help enforce and maintain security:

- Keep all anti-virus, anti-malware software up to date.
- Allow PCs to regularly accept patches and security updates.
- Review and evaluate security notes and warnings from Apple, Google, and Microsoft for potential risks.
- Regularly review all accounts to keep to a minimum, and remove all unused accounts.
- Avoid sharing accounts (through creation of the shared email account for one time tokens).
- Specify only corporate unique issued email as email destination for one time tokens.
- Avoid using the same login credentials in Application portal as used on internal systems (including email passwords).

It is recommended that mobile devices are kept protected (locked) with a password or fingerprint detection. Use the device's auto-lock feature to require a password to unlock after 30 seconds of inactivity and don't share the device with others. Additionally, it is recommended that mobile device operating systems, applications, and security feature be kept up to date. Security features should not be overridden.

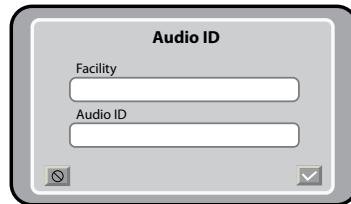
Note:

- The monitor screen requires a light touch, pressing too hard will damage LED screen
- Per standard procedure, after 2 minutes of no activity the user will need to confirm activity or log back in

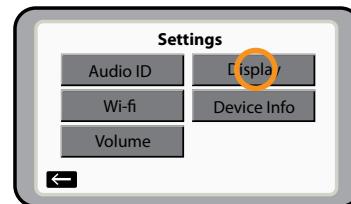
For detailed instructions on configuring other types of networks and additional recommendations regarding device cybersecurity, refer to the GEM FLOW COUPLER Monitor IT Setup Guide (MS-14193).

Troubleshooting

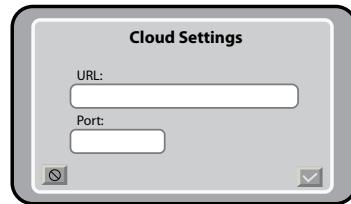
Common Issues and Screens to Verify:



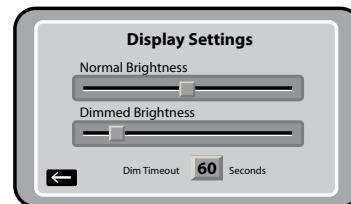
Facility and Audio ID fields must be filled out



The Display brightness can be adjusted through the Display button



Verify that the URL and Port fields are correct.



Brightness Adjustments

Wi-Fi will not connect.

- Possible cause: Audio ID and/or Facility information has not been entered. These are user entered; verify the appropriate text to be entered with hospital staff.
- Possible cause: Cloud URL or port number is not correct. Verify the URL and port numbers with Tech Support.

No audio is downloaded to the app.

- Possible cause: Audio ID and/or Facility information has not been entered. These are user entered; verify the appropriate text to be entered with hospital staff.
- Possible cause: a probe is not physically connected to the Channel of the GEM FLOW COUPLER Monitor. Verify with hospital.



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Please contact Customer Service for Instructions for Use (IFU).
Call 800.510.3318 or email smca_information@baxter.com

Rx Only. For safe and proper use of this system, refer to the Instructions for Use.

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